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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,009	06/18/2003	Kenneth David Becker	17100-009002 /37481-3308B	4986

20985 7590 03/16/2006

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,009	BECKER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-242* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-242* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-32, claims 1-14, 16-22, 24-47, 49-61, 63-75, drawn to isolated nucleic acids, vectors, host cells, primer or probes, and kits, wherein Groups 1-32 are single nucleotide polymorphic (SNP) position such as position 122260 of SEQ ID No. 484 is Group I, position 122256 of SEQ ID No. 484 is Group 2.....position 41014 of SEQ ID No. 347 is Group 6, position 41015 of SEQ ID No. 347 is Group 7, etc., classified in class 536, subclass 23.1, 22.1, class 435 subclass 320.1. ***Groups 33-43***, claims 76-113, drawn a method for detecting the presence or absence of a polymorphism of a KNSL1 gene, classified in class 435, subclass 6, wherein Groups 33-43 are SNPs such as in claim 76, with Group 33 being a method with a nucleotide molecule corresponding to positions 41014 of SEQ ID No. 347, Group 34 being a method with a nucleotide molecule comprising position 41015 of SEQ ID No. 347, and so on.

Groups 44-85, claims 114-242, drawn to a method of screening for agents, wherein Groups 44-85 are the method with SNPs such as in claim 114, with Group 44 being the position 122260 of SEQ ID No. 484, Group 45 being 122256 of SEQ ID NO. 484, etc., classified in class 436, subclass 503, and subclass 63.

Groups 86-91, claims 15, 23, 48, 62, drawn to transgenic animals, wherein Groups 86-91 are the transgenic animals with SNPs such as in claim 15, with Group 86 being position 122260 of SEQ ID No. 484, Group 87 being position 122256 of SEQ ID No. 484, etc., classified in class 800, subclass 278.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-91 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each Group is unrelated to one another as they utilize different products, which demonstrate that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for each invention differ significantly from one another. Therefore, each invention is divergent in materials and steps. For these reasons each of these Inventions are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search all these inventions together. In addition, each SNP position is assigned one Group as they comprise patentably distinct SNPs or mutations of a sequence. These SNPs or mutations result in patentably distinct sequences with different structures. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Inventions in Groups 1-32 and 33-43 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (nucleic acids) of Group I can be used to in materially different processes such as nucleic acid purification or ligand binding assays as opposed to its use in detecting the occurrence of polymorphism in KNSL1 gene.

Searching the inventions of Groups 1-32 and 33-43 together would impose serious search burden. The inventions of Groups 1-32 and 33-43 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the method of detecting the occurrence of polymorphism in KNSL1 gene and the products are not coextensive. Groups 33-43 encompass method steps for detecting the occurrence of polymorphism in KNSL1 gene, which are not required for the search of Groups 1-32. In contrast, the search for Groups 1-32 would require a text search for the use of the products in addition to a search for the products. Prior art, which teaches a product, would not necessarily be applicable to the method of detecting the occurrence of polymorphism in KNSL1 gene. Moreover, even if the product were known, the method of detecting the occurrence of polymorphism in KNSL1 gene may be novel and unobvious in view of the preamble or active steps.

Inventions in Groups 1-32 and 44-85 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the product (nucleic acids) of Group I can be used to in materially different processes such as nucleic acid purification or ligand binding assays as opposed to its use in screening for an agent that modulates the expression and / or activity of IDE.

Searching the inventions of Groups 1-32 and 44-85 together would impose serious search burden. The inventions of Groups 1-32 and 44-85 have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the method of screening for an agent that modulates the expression and / or activity of IDE and the products are not coextensive. Groups 44-85 encompass method steps for screening for an agent that modulates the expression and / or activity of IDE, which are not required for the search of Groups 1-32. In contrast, the search for Groups 1-32 would require a text search for the use of the products in addition to a search for the products. Prior art, which teaches a product, would not necessarily be applicable to the method of screening for an agent that modulates the expression and / or activity of IDE. Moreover, even if the product were known, the method of screening for an agent that modulates the expression and / or activity of IDE may be novel and unobvious in view of the preamble or active steps.

Inventions 1-32 and 86-91 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The nucleic acids of Groups 1-32, and the transgenic animals of Groups are all unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent

material. Moreover, the methodology and materials necessary for manipulating a nucleic acid differ significantly for each of the materials. Therefore, each method is divergent in materials and steps. For these reasons each of these Inventions are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search the inventions of Groups 1-237, 528-777,1186-1453, 1460-1810 together.

Inventions 33-43 and 44-85, 86-91 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method for detecting the presence or absence of a polymorphism in KNSL1 gene (Groups 33-43), and the method for screening for an agent (Groups 44-85) and the transgenic animals (Groups 86-91) are all unrelated as they comprise distinct steps and utilize different products which demonstrate that each invention performs this function using a structurally and functionally divergent material. For these reasons each of these Inventions are patentably distinct. Furthermore, the distinct products require separate and distinct searches. As such, it would be burdensome to search the inventions of Groups 238-527, 778-1185, 1454-1456, and 1457-1459 together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of

the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prabha Chunduru
SURYAPRABHA CHUNDURU
PATENT EXAMINER 3/14/06